

SUMMARY OF SAFETY AND EFFECTIVENESS

K964485

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

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Submitter:

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Name of the Device: PORTpro Electronic Portal Imaging System

Predicate Devices: The PORTpro is substantially equivalent to a combination of the SRI 100 Radiotherapy Imaging System manufactured by Phillips Medical Systems and the Huestis Flexi-Holder manufactured by Huestis Medical Products.

Description of the Device: The PORTpro is a free-standing, digital camera based electronic portal imaging device (EPID) for use as an accessory to existing x-radiation therapy systems operating in the megavoltage range (1 - 15 MeV). The PORTpro displays high quality portal images on a computer monitor in virtually real time and also provides archiving and image processing capabilities. The real time display of images is advantageous insofar as treating physicians and therapy technicians are able to quickly produce position verification images without time consuming set up and development of radiographic films. This is helpful in radiation therapy since frequent monitoring of patient positioning can reduce the frequency of discrepancies in (x-ray) field placement, and improve geometric accuracy of the treatments.

Because the PORTpro has a free-standing detector support system, it offers advantages over other EPID's without this feature, i.e., easy positioning of the imaging system, adjustable and relatively large effective field of view, and the ability to do "non-couch" total body irradiation (TBI) and total lymphatic irradiation (TLI).

Comparison of Technological Characteristics:

Technological Characteristic	PORTpro	SRI 100	Flexi-holder
Acquisition regime	Full field	Full field	NA
Acquisition matrix	746 x 582	512 x 256	NA
Spatial resolution	1.0 mm	2.0 mm	NA
Pixel resolution (bits)	16	16	NA
High Voltage	No	No	No
CCD/Video	CCD	CCD	NA
Height	75"	NA	75"
Weight	136 lbs.	-----	110 lbs.
Base	14" x 30"	NA	19" x 22"

The differences between the systems raise no new issues of safety or effectiveness.

Date

Mr. Reuven Levinson, President